AVAILABLE INFORMATION ON ASSESSING EXPOSURE FROM PESTICIDES IN FOOD

A USER'S GUIDE

Response to Public Comments

Docket OPP-00576

Health Effects Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
Washington, DC 20460

June 21, 2000

Provided below are the Agency's responses to the comments submitted to docket OPP-00576 "A User's Guide to Available EPA Information on Assessing Dietary (Food) Exposure to Pesticides."

Rhône-Poulenc – 03

Comment 03-1. The commenter provided the following suggestions for clarification:

< Acute Reference Dose (section I.A.1.a). Mention the uncertainty factors in addition to the traditional intra- and interspecies factors.

< MOE, Threshold Cancer (section I.A.3.a). Note that this method is in transition and policy is now being developed by EPA in consultation with SAP.

< Basic Equations (section I.C). Only mentions DEEM™. Section should be revised to mention that EPA will accept any valid and defensible model that may be available in the future.

< Non-Threshold Cancer Risk (section I.C.2.a). Revise last sentence to read, "That is, for every one million exposed persons, one would expect, *at the most (upper bound)* one more cancer than would other wise occur, *and may be less.*"

< Data Sources, 40 CFR 158.240 (section II.A.1). The last paragraph should clarify that field trial data is "worst case" because maximum rates and PHI's are used as outlined on the label and many times this does not reflect actual or typical use rates.

< USDA Pesticide Data Program. This section should point out that samples are collected closer to the point of consumption than field trials, but are still not at the "grocery store" or "dinner plate" levels where residues may be reduced even further. Also, a statement should be added that the PDP program is now collecting some single serving data in addition to the traditional composite.

< Consumption Information. This section only mentions one model for use in dietary calculations and should be revised to be more general in what programs/models may be accepted.

Response. EPA has incorporated most of these clarifying comments into the revised paper, as appropriate.

EXTOXNET– 04

Comment 04-1. In summarizing its perception of how EPA approaches acute and chronic dietary risk assessment, the commenter stated that EPA generally does not use anticipated residue data in its acute food exposure assessment. As a result, Reregistration Eligibility Decision Documents for the organophosphates are meeting the benchmarks for chronic exposure but not for acute exposure. No specific comments or suggestions are provided.

Response. EPA disagrees. The Agency routinely uses all available reliable residue data, including percent of crop treated, processing studies, and monitoring data in its acute and chronic refined assessments for exposure resulting from pesticide residues in food, which are done using EPA's tiered approach (for a good description of the tiering, see "Classification of Food Forms With Respect to Level of Blending. HED Standard Operating Procedure 99.6 (8/20/99);" (EPA, 1999a)). A reference for SOP 99.6 has been added to the revised paper.

In assessing risk resulting from exposure to pesticide residues in food, acute exposure estimates are calculated a little differently from chronic exposure estimates. As the paper points out, in an acute exposure assessment, the risk assessor is attempting to estimate how much of a pesticide residue might be consumed in a single day. Acute exposure calculations employ a full range of data including high-end residue values, high-end consumption, and high-end %CT estimates. For a chronic exposure assessment, the risk assessor is attempting to estimate how much pesticide residue might be consumed on a daily basis over the course of a lifetime. Consequently, these use average residue values, average consumption values, and average %CT estimates. So, even though acute and chronic exposures are refined differently from each other, refinements are indeed made for acute exposure assessments.

A good example of how anticipated residues were calculated for an acute assessment under the tiering system is “Phosmet...HED Revised Human Health Risk Assessment for the Reregistration Eligibility Decision Document (RED)...;” (EPA, 2000a).

Comment 04-2. In its risk management decisions, EPA generally uses a benchmark of 100 fold below the NOEL; this is purely arbitrary and assumes all physiological responses are linear with dose.

Response. In its dose-response assessment for pesticide chemicals, EPA applies several factors to the NOAEL including: 100-fold in uncertainty factors (10-fold to account for variation within the human population—intraspecies; and 10-fold to account for the differences between humans and animals as the animal data are translated to humans—interspecies); additional uncertainty factors, and an FQPA Safety Factor. EPA disagrees that these factors are purely arbitrary. The inter- and intraspecies uncertainty factors are standard practice in the risk assessment and have been endorsed by the National Academy of Sciences. Consideration of the FQPA Safety Factor is required by statute. The Agency’s application of the FQPA Factor, along with the uncertainty factors, has been reviewed by the FIFRA Scientific Advisory Panel.

Comment 04-3. It is not clear from the science policy statements when information to more accurately determine anticipated residues will be considered acceptable for use in refining risk assessments. The policy states that scientific judgement will be used to assess appropriateness of the data, but it is unclear what this really means. Further, the commenter notes that EPA’s Framework document (10/98) indicated that this paper would provide guidance for growers...when collecting certain residue information.

Response. As the commenter stated, in the original October 1998 Framework document the Agency did indicate that it “would provide guidance for growers...when collecting certain residue information” related to supplying information to the Agency that can be used in refining anticipated residues.

EPA has prepared two papers (which have been through public comment and response) to provide growers with more information and guidance on providing information that can be used in refining the exposure estimates. The first paper—"The Role of the Use-Related Information in Pesticide Risk Assessment and Risk Management;" draft document (EPA, 1999b)—provides information on the types of use-related information (*e.g.*, typical use rates, percent of crop treated) that can be used in risk assessment and how this information is derived. The second paper "Guidance for Refining Anticipated Residue Estimates for Use in Acute Dietary Probabilistic Risk Assessment;" (EPA, 2000b)—provides guidance to registrants, other test sponsors and interested parties, and data reviewers on the extent and quality of pesticide residue and ancillary data needed to support the use of more refined "anticipated residues" in acute dietary probabilistic exposure assessments.

Both these papers are referenced and discussed in the revised "User's Guide."

Comment 04-4. DRES data are old and the U.S. food consumption pattern has changed since 1977.

Response. EPA agrees with the commenter—The Dietary Risk Evaluation System (DRES) data are old and the food consumption patterns for the U.S. have indeed changed since 1977. USDA periodically updates its food consumption information by conducting its Continuing Survey of Food Intake by Individuals. The current model used to assess risk resulting from exposure to pesticide residues in food (*i.e.*, DEEM™) uses the 1988-1991 CSFII data. Soon, it will be updated by the 1994-1996 CSFII data. Additionally, USDA has conducted a Children's Supplemental Survey that will also be added to DEEM™. All mention of DRES has been removed from the paper; it has been updated to reflect the latest in food consumption information.

Comment 04-5. Details are lacking regarding how and when data will be considered to be acceptable to be used to refine exposure assessments.

Response. EPA has prepared the following guidance paper to provide this type of information: “Guidance for Refining Anticipated Residue Estimates for Use in Acute Dietary Probabilistic Risk Assessment;" (EPA, 2000b). It is referenced and discussed in the revised “User’s Guide.”

Comment 04-6. The release of the User’s Guide did not clarify, but rather confused, several of the issues surrounding both acute and chronic food exposure estimates. The commenter pointed out that many of the referenced documents are old and should be updated. Also, the commenter pointed out that there is some inconsistency among the policies discussed in the various documents.

Response. EPA notes the comments and has checked to make sure that the referenced documents are the latest available and are not contradictory.

Novartis Crop Protection – 05 (also, L001)

Comment 05-1. Dietary exposure should be assessed using the most scientifically valid methodology available.

Response. The Agency agrees. The revised paper reflects EPA’s latest guidance in this area.

Comment 05-2. Comments were submitted on cumulative risk, aggregate risk, and the draft Cancer Risk Assessment Guidelines.

Response. All these science policy areas are being addressed at length in separate science policy documents going through a process providing public notice and opportunity to comment. Regarding cumulative, EPA plans to issue a draft document shortly. With respect to aggregate, a draft document entitled "Guidance for Performing Aggregate Exposure and Risk Assessment" was issued on January 5, 2000 and announced in a *Federal Register Notice* (65 FR 459).

The aggregate and cumulative documents are policies specifically relating to the regulation of pesticide chemicals; they are being drafted by EPA's Office of Pesticide Programs. The Cancer Guidelines apply Agency-wide; EPA's Office of Research and Development has the lead. The last draft, which incorporated public comments received under a 1996 Federal Register notice, was issued in July 1999. At that time it was also submitted to EPA's Science Advisory Board for specific comment on the provisions and guidance to ensure protection of the fetus, infants and children.

Comment 05-3. Regarding the DEEM™ software, the Agency should allow for scientific advances in software development that will provide additional tools that may, among other things, be capable of performing routine sensitivity analyses for the identification of potential risk drivers; this is not practical with the current version of DEEM™.

Response. The DEEM™ software has been updated to perform sensitivity analyses. EPA routinely conducts such analyses when there are exposures and risks of concern. We have added this fact to the paper.

Comment 05-4. EPA should not limit the dietary risk software tools, but rather design a transparent, workable process for determining acceptability of alternative models for evaluation of dietary exposure.

Response. EPA encourages individuals to submit alternative validated and peer-reviewed models for assessing risk that results from exposure to pesticide residues in food. Any submitted model would be subject to public comment, including review by the FIFRA Scientific Advisory Panel (SAP).

Comment 05-5. EPA should mandate that all of the software used in the assessments be publicly available with transparent source code and databases.

Response. EPA is moving is this direction. EPA is currently using a software program called DEEM™—a proprietary product of Novigen, Inc. While DEEM™ is publicly available, the proprietary nature of the product prohibits the Agency from making the source code publicly available. But, as part of its presentation at the March 1, 2000 SAP meeting, Novigen made some of its source code publicly-available (http://www.epa.gov/scipoly/sap/index.htm).

The food consumption data that go into the model are available from USDA. USDA samples in terms of amount of "pizza" and "beef stew" consumed; EPA needs this information in terms of the individual commodities such as flour, tomato, meat, and vegetables. USDA and EPA have just completed a joint project where the USDA data have been converted to raw agricultural commodities using standard translation recipes. This information is being put into DEEM™ and it is publicly-available.

EPA is supporting the efforts of Hampshire Research Inc. (HRI) in their development of a software program for estimating exposure to pesticides in food, water, and as a result of use in and around residential and similar sites. The HRI software program, when completed, will be available to the public and its program codes will be fully transparent.

REFERENCES

EPA, 1999a. “Memorandum from Margaret Stasikowski, Director Health Effects Division to Health Effects Division Staff. “Classification of Food Forms With Respect to Level of Blending. HED Standard Operating Procedure 99.6 (8/20/99);” August 20, 1999.

EPA, 1999b. “The Role of the Use-Related Information in Pesticide Risk Assessment and Risk Management;" draft document. June 29, 1999. http://www.epa.gov/oppbead1/use-related.pdf (64 FR 37977)

EPA, 2000a. Memorandum from Christina Swartz to Diane Isbell/Kathy Monk. “Phosmet (Chemical ID No. 059201/List A Reregistration Case No. 0242). HED Revised Human Health Risk Assessment for the Reregistration Eligibility Decision Document (RED). DP Barcode No. D262365.” February 9, 2000. http://www.epa.gov/pesticides/op/phosmet.htm

EPA, 2000b. "Guidance for Refining Anticipated Residue Estimates for Use in Acute Dietary Probabilistic Risk Assessment;" June 15, 2000. (65 FR 39147). http://www.epa.gov/fedrgstr/EPA-PEST/2000/June/Day-23/o-p15917.htm